Sheet 1 of 7 Docket Number (Optional) Form PTO-1449 **Application Number** 3833.9US Not yet assigned INFORMATION DISCLOSURE CITATION Applicant Fallaux et al. IN AN APPLICATION (Use several sheets if necessary) Filing Date July 11, 2003 Group Art Unit Unknown **U.S. PATENT DOCUMENTS** EXAMINER FILING DATE DOCUMENT NUMBER DATE CLASS SUBCLASS INITIAL IF APPROPRIATE #4,405,712 09/20/83 Vande Woude et al. #4,497,796 02/05/85 Salser et al. #4,727,028 02/23/88 Santerre et al. #4,740,463 04/26/88 Weinberg et al. #5,190,931 03/02/93 Inouye #5,208,149 05/04/93 Inouye #5,378,618 01/03/95 Sternberg et al. #5,518,913 05/21/96 Massie et al. #5,545,522 08/13/96 Van Gelder et al. #5,652,224 07/29/97 Wilson et al. #5,670,488 09/23/97 Gregory et al. FOREIGN PATENT DOCUMENTS Translation DOCUMENT NUMBER DATE COUNTRY CLASS SUBCLASS NO #2,053,187 04/11/93 Canada #WO 94/08026 04/14/94 **PCT** 05/26/94 #WO 94/11506 **PCT** #WO 94/12649 06/09/94 **PCT** #WO 94/23582 10/27/94 PCT OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) #Amalfitano et al., "Improved adenovirus packaging cell lines to support the growth of replication-defective gene-delivery vectors", Proc. Natl. Acad. Sci. USA, 93:3352-3356, April 1996. #Amalfitano et al., "Isolation and characterization of packaging cell lines that coexpress the adenovirus E1, DNA polymerase, and preterminal proteins: implications for gene therapy", Gene Therapy, 4:258-263, 1997. #Armentano et al., "Characterization of an Adenovirus Gene Transfer Vector Containing an E4 Deletion", Human Gene Therapy, 6:1343-1353, October 1995. **EXAMINER DATE CONSIDERED** 1/129/04 EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

Sheet 2 of 7 Docket Number (Optional) Form PTO-1449 **Application Number** 3833.9US Not yet assigned INFORMATION DISCLOSURE CITATION IN AN APPLICATION Applicant Fallaux tal. (Use several sheets if necessary) Group Art Unit Unknown Filing Date July 11, 2003 **U.S. PATENT DOCUMENTS** EXAMINER FILING DATE
IF APPROPRIATE DOCUMENT NUMBER DATE NAME CLASS SUBCLASS INITIAL (01 #5,707,618 01/13/98 Armentano et al. #5,753,500 05/19/98 Shenk et al. 11/17/98 #5,837,511 Falck-Pedersen et al. #5,851,806 12/98 Kovesdi et al. #5,891,690 04/99 Massie #5,919,676 07/99 Graham et al. #5,994,106 11/30/99 Kovesdi et al. #5,994,128 11/30/99 Fallaux et al. #6,033,908 03/07/2000 Bout et al. #6,040,174 03/21/2000 Imler et al. #6,203,975 03/2001 Wilson 6,265,212 07/24/2001 Fallaux et al. FOREIGN PATENT DOCUMENTS DOCUMENT NUMBER DATE COUNTRY CLASS SUBCLASS #WO 94/24297 10/27/94 **PCT** #WO 94/26914 11/24/94 PCT #WO 94/28152 12/08/94 PCT #WO 94/28938 12/22/94 PCT **OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.) #Bernards, Rene, et al., "Characterization of Cells Transformed by Ad5/Ad12 Hybrid Early Region I Plasmids", Virology ,120:422-432, 1982. #Bernards, Rene, et al., "Role of Adenovius Types 5 and 12 Early Region 1b Tumor Antigens in Oncogenic Transformation", Virology, 127:45-53, 1983. #Brough et al.,"A Gene Transfer Vector-Cell Line System for Complete Functional Complementation of Adenovirus Early Regions E1 and E4", Journal of Virology, 70(9):6497-6501. September 1996. **EXAMINER DATE CONSIDERED** EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

Docket Number (Optional) **Application Number** Form PTO-1449 3833.9US Not y tassigned INFORMATION DISCLOSURE CITATION Applicant Fallaux et al. IN AN APPLICATION (Use several sheets if necessary) Filing Date July 11, 2003 Group Art Unit Unknown **FOREIGN PATENT DOCUMENTS** Translation DOCUMENT NUMBER CLASS DATE COUNTRY SUBCLASS NO YES (BV) #WO 95/00655 01/05/95 **PCT** #2 707 664 01/20/95 France #WO 95/02697 01/26/95 **PCT** 06/15/95 #95201611.1 EP #WO 95/16772 06/22/95 PCT 06/26/95 EP #95201728.3 #2,117,668 09/10/95 Canada #WO 95/26411 10/05/95 **PCT** #WO 95/27071 10/12/95 **PCT** #WO 95/34671 12/21/95 **PCT** #AU-A-28533/95 03/21/96 Australia #WO 96/13596 05/09/96 **PCT** #WO 96/14061 05/17/96 **PCT** #WO 96/16676 06/06/96 **PCT** #WO 96/18418 06/20/96 **PCT** #WO 96/33280 10/24/96 PCT #WO 96/40955 12/19/96 **PCT OTHER DOCUMENTS** (Including Author, Title, Date, Pertinent Pages, Etc.) #Brough et al., "Construction, Characterization, and Utilization of Cell Lines Which Inducibly Express the Adenovirus DNA-Binding Protein", Virology, 190:624-634, 1992. #Brough et al., "Multiple Functions of the Adenovirus DNA-Binding Protein Are Required for Efficient Viral DNA Synthesis", Virology, 196:269-281, 1993. #Brough et al., "Restricted changes in the adenovirus DNA-binding protein that lead to extended host range or temperature sensitive phenotypes", Journal of Virology, Vol. 55, pp. 206-212. DATE CONSIDERED **EXAMINER** EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through conformance and not considered. Include copy of this form with next communication to the applicant.

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Form PTO-1449			Docket Number (Optional) 3833.9US		Application Number Not yet assigned				
INFORMATION DISCLOSURE CITATION IN AN APPLICATION			Applicant Fallaux et al.						
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∞ \				or Complementation of Acrence On Gene Therapy,			ns E1, E2	? A	
·	Line Com	#Caravokyri et al., "Constitutive Episomal Expression of Polypeptide IX (pIX) in a 293-Based Cell Line Complements the Deficiency of pIX Mutant Adenovirus Type 5", <u>Journal of Virology</u> , 69(11):6627-6633, November 1995.							
	persisten	#Engelhardt et al., "Ablation of E2A in recombinant adenoviruses improves transgene persistence and decreases inflammatory response in mouse liver", <u>Proceeding of the National Sciences of USA</u> , Vol. 91, pp. 6196-6200, 1994.							
		#Fallaux et al., "Characterization of 911: A New Helper Cell Line for the Titration and Propagation of Early Region 1-Deleted Adenoviral Vectors", Human Gene Therapy, 7:215-222,							
	#Fields et	#Fields et al., "Fields Virology", Second Edition, pp. 28-30, 87.							
		#Fisher et al., "Recombinant Adenovirus Deleted of All Viral Genes for Gene Therapy of Cystic Fibrosis", Virology, 217:11-22, 1996.							
/		#Gao et al., "Biology of Adenovirus Vectors with E1 and E4 Deletions for Liver-Directed Gene Therapy", <u>Journal of Virology</u> , <u>70</u> (12):8934-8943, December 1996.							
		#Gorziglia et al., "Elimination of both E1 and E2a from Adenovirus Vectors Further Improves Prospects for In Vivo Human Gene Therapy", <u>Journal of Virology</u> , <u>70</u> (6):4173-4178, June 1996.							
	#Graham, F.L., et al., "Characteristics of a Human Cell Line Transformed by DNA from Human Adenovirus Type 5", <u>J. gen. Virol.</u> , 36:59-74, 1977.								
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(Use s	eeveral sheets if necessary)	Filing Date July 11, 2003	Group Art Unit Unknown		
	OTHER [OCUMENTS (Includi	ng Author, Title, Date, Pertinent Pages, Etc.)		
m)	#Grodzicker, Terri, et al., "Expression of Unselected Adenovirus Genes in Human Cells Cotransformed with the HSV-1 tk Gene and Adenovirus 2 DNA", Cell, 21:453-463, September 1980.				
·	#Hardy et al., "Construction of Adenovirus Vectors through Cre-lox Recombination", <u>Journal of Virology</u> , <u>71(3)</u> :1842-1849, March 1997.				
	#Hehir et al., "Molecular Characterization of Replication-Competent Variants of Adenovirus Vectors and Genome Modifications To Prevent Their Occurrence", <u>Journal of Virology</u> , <u>70</u> (12):8459-8467, December 1996.				
	#Imler et al., "Novel complementation cell-lines derived from human lung carcinoma A549 cells support the growth of E1-deleted adenovirus vectors", <u>Gene Therapy</u> , <u>3</u> :75-84, 1996.				
	#Kornberg, Arthur, "DNA Replication", W.H. Freeman and Company, San Francisco, 4 pages (double sided).				
	#Krougliak et al., "Development of Cell Lines Capable of Complementing E1, E4, and Protein IX Defective Adenovirus Type 5 Mutants", <u>Human Gene Therapy</u> , <u>6</u> :1575-1586, December 1995.				
	#Lemarchand et al., "Adenovirus-mediated transfer of a recombinant human α1-antitrypsin cDNA to human endothelial cells", Proc. Natl. Acad. Sci. USA, Vol. 89, pp. 6482-6486, July 1992.				
	#Lieber et al., "Recombinant Adenoviruses with Large Deletions Generated by Cre-Mediated Excision Exhibit Different Biological Properties Compared with First-Generation Vectors In Vitro and In Vivo", <u>Journal of Virology</u> , <u>70</u> :8944-8960, December 1996.				
	#Lochmuller, H., et al., "Emergence of Early Region 1-Containing Replication-Competent Adenovirus in Stocks of Replication-Defective Adenovirus Recombinants (ΔΕ1+ΔΕ3) During Multiple Passages in 293 Cells", Human Gene Therapy, 5:1485-1491, December 1994.				
	#Louis, Nathalie, et al., "Cloning and Sequencing of the Cellular-Viral Junctions from the Human Adenovirus Type 5 Transformed 293 Cell Line", Virology, 233:423-429, 1997.				
/	#Ngo et al., "in The Protein Folding Problem and Tertiary Structure Prediction", Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495, 1994.				
	#Orkin et al., "Reports and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy", 21 pages, December 7, 1995.				
EXAMINER	Dah	DATE CONSIDERED	129/04		
citation if not in	citation considered, whether or not citation considered. Include copy of this form				

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Form PTO-1449	Docket Number (Optional) 3833.9US	Application Number Not yet assigned			
INFORMATION DISCLOSURE CITATION IN AN APPLICATION	Applicant Fallaux et al.				
(Use several sheets if necessary)	Filing Date July 11, 2003	Group Art Unit Unknown			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Page					
#Roberts, Bryan E., et al., "Individu Distinct Alterations of Cellular Mort 413, Nov. 1985.	#Roberts, Bryan E., et al., "Individual Adenovirus Type 5 Early Region 1A Gene Products Elicit Distinct Alterations of Cellular Morphology and Gene Expression", <u>Journal of Virology</u> , pp. 404-413, Nov. 1985.				
#Rosenfeld et al., "In Vivo Transfel Regulator Gene to the Airway Epitl	#Rosenfeld et al., "In Vivo Transfer of the Human Cystic Fibrosis Transmembrane Conductance Regulator Gene to the Airway Epithelium", Cell, Vol. 68, pp. 143-155, January 10, 1992.				
#Sabatie et al., "Process Developm Vectors for Gene Transfer in Clinic <u>Technology</u> , BI-3, 1996.	#Sabatie et al., "Process Development for the Production of Second Generation Adenovirus Vectors for Gene Transfer in Clinical Protocols", <u>Abstract Book 14th Meeting on Animal Cell Technology</u> , BI-3, 1996.				
#Schaack et al., "Adenovirus Type Lines", <u>Journal of Virology</u> , <u>69</u> (7):4	#Schaack et al., "Adenovirus Type 5 Precursor Terminal Protein-Expressing 293 and HeLa Cell Lines", <u>Journal of Virology</u> , <u>69</u> (7):4079-4085, July 1995.				
#Stratford-Perricaudet, Leslie, et al Human Gene Transfer", 219:51-61	#Stratford-Perricaudet, Leslie, et al., "Gene Transfer Into Animals: The Promise of Adenovirus, Human Gene Transfer", 219:51-61, 1991.				
#Trapnell et al., "Gene therapy usir 5:617-625, 1994.	#Trapnell et al., "Gene therapy using adenoviral vectors", <u>Current Opinion in Biotechnology</u> , 5:617-625, 1994.				
#Vaessen, R.T.M.J., "Adenovirus E EMBO Journal, 5(2):335-341, 1986	#Vaessen, R.T.M.J., "Adenovirus E1A-Mediated Regulation of Class I MHC Expression", The EMBO Journal, 5(2):335-341, 1986.				
	#Vaessen, R.T.M.J., "Different Adenovirus E1A-Controlled Properties of Transformed Cells Require Different Levels of E1A Expression", <u>Gene</u> , pp. 247-254, 1987.				
#Vanhaesebroeck, Bart, et al., "Mo Action of Tumor Necrosis Factor by Virology, 176:362-368, 1990.	#Vanhaesebroeck, Bart, et al., "Modulation of Cellular Susceptibility to the Cytotoxic/Cytostatic Action of Tumor Necrosis Factor by Adenovirus E1 Gene Expression Is Cell Type-Dependent", Virology, 176:362-368, 1990.				
	#Vos et al., "Characterization of Adenovirus Type 5 Insertion and Deletion Mutants Encoding Altered DNA Binding Proteins", Virology, 172, pp. 634-642, 1989.				
#Wang et al., "A packaging cell line containing two lethal gene-region d	#Wang et al., "A packaging cell line for propagation of recombinant adenovirus vectors containing two lethal gene-region deletions", Gene Therapy, 2:775-783, 1995.				
#Weinberg et al., "A cell line that supports the growth of a defective early region 4 deletion mutant of human adenovirus type 2", Proc. Natl. Sci. USA, Vol. 80, pp. 5383-5386, September 1983.					
EXAMINER Davi	DATE CONSIDERED	11/29/04			
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.					

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		Filing Date July 11, 2003	Group Art Unit Unknown		
	OTHER I	OCUMENTS (Includ	ing Author, Title, Date, Pertinent Pages, Etc.)		
	#Yang et al., "Cellular immunity to viral antigens limits E1-deleted adenoviruses for gene therapy", Proc. Natl. Acad. Sci. USA, Vol. 91, pp. 4407-4411, May 1994.				
	#Yeh et al., "Efficient Dual Transcomplementation of Adenovirus E1 and E4 Regions from a 293-Derived Cell Line Expressing a Minimal E4 Functional Unit", <u>Journal of Virology</u> , <u>70(1):559-565</u> , January 1996.				
N	#Zhou et al., "Development of a Complementing Cell Line and a System for Construction of Adenovirus Vectors with E1 and E2a Deleted", <u>Journal of Virology</u> , <u>70(1)</u> :7030-7038, October 1996.				
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citation if not in	f citation considered, whether or not citation considered. Include copy of this form		•		

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#Pursuant to 37 C.F.R. § 1.98(d), copies of the previously identified patents are <u>not</u> being provided since they were previously cited by or submitted to the Office in the following prior applications:

Serial No.: 10/219,414 Filed: 8/15/2002

For: STOCKS OF REPLICATION DEFICIENT ADENOVIRUS, which application is being relied upon for an earlier filing date under 35 U.S.C. § 120.